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APPLICATION NO.	FILING DAT	E	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	. CONFIRMATION N			
10/618,941	0/618,941 07/15/200		David Whyte	034536-0321	6608			
22428	7590 01/2	24/2006		EXAM	INER			
FOLEY AN	D LARDNER I	LLP		MONSHIPOUR	U, MARYAM			
3000 K STRE	ET NW			ART UNIT	PAPER NUMBER			
WASHINGT	ON, DC 20007			1653				

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)										
Office Action Commons	10/618,941	WHYTE ET AL.										
Office Action Summary	Examiner	Art Unit										
	Maryam Monshipouri	1653										
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence ad	dress									
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D. Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timused and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	l. lely filed the mailing date of this co										
Status												
1) Responsive to communication(s) filed on												
· <u> </u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is											
, ===	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.											
Disposition of Claims												
4)⊠ Claim(s) <u>1-36</u> is/are pending in the application												
4a) Of the above claim(s) <u>6-25 and 30-36</u> is/are												
5) Claim(s) is/are allowed.	s withdrawn from consideration.											
6)⊠ Claim(s) <u>1-5 and 26-29</u> is/are rejected.		•										
7) Claim(s) is/are objected to.												
8) Claim(s) are subject to restriction and/o	r election requirement											
o) Claim(s) are subject to restriction and/o	r election requirement.											
Application Papers												
9)☐ The specification is objected to by the Examine	r.											
10) The drawing(s) filed on is/are: a) acc	epted or b) \square objected to by the $\mathfrak l$	Examiner.										
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37. CFR 1.85(a).										
Replacement drawing sheet(s) including the correct	tion is required if the drawing(s) is obj	ected to. See 37 CF	R 1.121(d).									
11) The oath or declaration is objected to by the Ex	caminer. Note the attached Office	Action or form PT	O-152.									
Priority under 35 U.S.C. § 119												
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.												
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) ☐ Interview Summary Paper No(s)/Mail Da 5) ☐ Notice of Informal P 6) ☑ Other: <u>১০</u> ১ మ	ite atent Application (PTC)-152)									

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Applicant's response to restriction requirement filed 12/9/2005 is acknowledged.

Applicant elected Group I (claims 1-5, 26-29, SEQ ID NO99 only) with traverse. In traversal of restriction requirement applicant argues that the requirement to elect a single sequence runs counter to the PTO's own policy that "up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction," to aid biotechnology industry "without creating an undue burden on the Office". According to applicant the Office has failed to articulate any justification for suspending that policy in this case. In view of applicant the Office has not established that the sequences in this application are any more difficult to examine than those in a "biotechnology case " thereby making it unreasonable to examine more than a single sequence. Accordingly, applicant request withdrawal and revision of the restriction requirement.

These arguments wren fully considered but were found **unpersuasive** for the following reasons: Firstly the examiner respectfully disagrees with the applicant that electing a single sequence runs counter to the office policy. This is because said policy does not bar examining a single invention in a single application. Secondly, said policy does not specify that distinct sequences are directed to patentably distinct inventions. The major restriction criteria applied to this instant invention is based on patentably distinct inventions rather than patentably distinct sequences, which allows for an appropriate search and examination of each invention leading to issuance of valid patents which in its turn aids the biotechnology industry much more than incompletely searching many patentably distinct inventions in a single application. Applicant is well

aware of the exponential growth of commercially available sequence databases since the time of establishment of said policy i.e. 11/1996, and she/he can surely appreciate that searching any additional sequences (inventions) in the instant databases does requires many hours of additional sequence searching as well as key word searching, which **does impose an undue burden** of searching on the examiner and is not even required by the criteria set forth in 35 USC section 121.

Therefore, in view of arguments provided above and in view of MPEP criteria set forth for restriction shown in the previous office action, the examiner finds no reason to withdraw the restriction requirement, which is now **Final**.

DETAILED ACTION

Claims 1-5, 26-29, (SEQ ID NO:99 only) are under examination on the merits.

Claims 6-25, 30-36 and SEQ ID NO:67-98, 100-132 are withdrawn as drawn to non-elected invention.

Claim Objections

Claims 1-5, 26-29 are objected to because of the following informalities: said claims still recite non-elected subject matter, namely SEQ ID NO:67-98, 100-132.

Applicant is advised to delete non-elected subject matter from said claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "N-terminal domain", "C-terminal catalytic domain", "C-terminal domain" etc. in claim 1 and its dependent claims 2-5, 28 - 29 are unclear. In page 22 some of these terms have been defined. However, for example, it is unclear whether "N-terminal region" and "N-terminal domain" are identical or different. Further even if one assumes that said terms are identical the definition provided is non-specific to the instant invention. Again looking at the definition of "N-terminal region", it is unclear where the catalytic domain of SEQ ID NO:99 starts and where exactly in between the initiator methionine and catalytic domain applicant is referring to. These problems also exist with all the other terms recited in claim 1. Appropriate clarification is required.

Claims 1-5, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 as recited requires that all parts (a)-(d) encode kinases by recitation of activity in the preamble. Thus, it is believed that recitation of activity in claim 1(c) is redundant. Further, if one assumes that the function in the preamble may be applied to parts (a)-(e) of claim 1 it s unclear how a polypeitde that lacks catalytic domain (see part (d)) can retain kinase function.

Claims 2-5 and 28-29 are merely rejected for depending from are rejected base claim 1.

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Claims 2 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2 applicant is claiming the nucleic acid of claim 1 comprising a vector while in claim 29 he/she is claiming a vector comprising the same nucleic acid. It is unclear if in both claims vectors are identical structures or different. Appropriate clarification is required.

Claims 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "consisting essentially of " in claims 26-27 is confusing. In page 254 applicant has defined said term as to be replaceable by "consisting of" or comprising" and refers to said terms as terms of description and not limitation. As applicant is well aware MPEP interprets the term "consisting essentially of" as open language and said term can only be replaced by "comprising" and not by "consisting of" which is closed language and is a limiting term. Hence, for examination purposes "consisting essentially of" is assumed to have the same meaning as "comprising". Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids having SEQ ID NO:33 or

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encoding SEQ ID NO:99, does not reasonably provide enablement for any isolated nucleic consisting essentially of 10-30 bases of a sequence encoding SEQ ID NO:99 or consisting essentially of 10-30 bases of SEQ ID NO:33.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which additional residues beyond the 10-30 bases defined in claimed probes is in charge of assigning kinase function to said products. No examples of such residues are provided either. Current state of the art indicates that for nucleic acid probe to retain any function it must at least encode the catalytic region.

Such region in the case of kinases is typically 250-300 amino acids long, which requires a nucleic acid length of 750-900 contiguous bases.

Therefore, due to lack of sufficient information and examples provided in the specification and due to unpredictability of prior art as to which residues beyond the 10-30 contiguous residues of SEQ ID NO:33 or those encoding SEQ ID NO:99 should be retained in the claimed probes such that they encode kinases one of skill in the art has to go through the burden of undue experimentation in order to screen for those probes that are within the scope of this invention and as such the claims are not fully enabled.

Claims 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 26-27 are each direct to a genus of nucleic acids that have not been adequately described in the specification.

The specification does not contain any disclosure of the function of all DNA sequences that are consisting essentially of 10-30 contiguous residues of SEQ ID NO:33 or are consisting essentially of 10-30 residues of a DNA sequence encoding SEQ ID NO:99. The genus of cDNAs that consists essentially of these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of each claimed genus (DNA encoding SEQ ID NO:99 and SEQ ID NO:33) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 26-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Furness et al. (U.S. patent No. 6,673,549, issued 1/2004). Furness teaches a human DNA sequence (see its SEQ ID NO:1053) which inherently encodes a kinase product having 97.8% identity to SEQ ID NO:99 of this invention and its sequence does hybridize to the DNA sequence encoding SEQ ID NO:99 under stringent conditions (see the attached sequence alignment) anticipating claims 1, 4-5 and consists essentially of 10-30 contiguous nucleotides of SEQ ID NO:33 or that encoding SEQ ID NO:99 anticipating claims 26-27. In columns 17-18, Furness teaches about vectors and host cells comprising its DNA sequences anticipating claims 2-3 and 28-29.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al. (WO200073469, 12/2000). Plowman teaches a DNA sequence (see its SEQ ID NO:61) that encodes a human kinase and hybridizes to a DNA sequence (see the attached sequence alignment) encoding SEQ ID NO:99 under stringent conditions, anticipating claims 1, 4-5. Its sequence consists essentially of 10-30 residues of SEQ ID NO:33 or that encoding SEQ ID NO:99 anticipating claims 26-27. In pages 32-35, Plowman teaches about vectors and host cells comprising its DNA sequences anticipating claims 2-3 and 28-29.

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No claims are allowed.

Allowable Subject Matter

Isolated DNA sequences encoding SEQ ID NO:99 or comprising SEQ ID NO:33

are free of prior art. Further, the prior art does not teach or suggest preparing such

specifically claimed DNA sequences. Hence said sequences are also non-obvious.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Maryam Monshipouri whose telephone number is (571)

272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for

alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner

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Result
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ALIGNMENTS

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GENERAL INFORMATION:
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APPLICANT: Buchbinder, Jenny
TITLE OF INVENTION: GENES EXPRESSED IN C3A LIVER CELL CULTURES TREATED WITH
FILE REFERENCE: PA-0041 US
CURRENT APPLICATION NUMBER: US/09/976,594
CURRENT FILING DATE: 2001-10-12
CURRENT FILING DATE: 2001-10-12
                                                                                                                                                                                                                                                                 PRIOR APPLICATION NUMBER: 60/240,409
PRIOR FILING DATE: 2000-10-12
NUMBER OF SEC ID NOS: 1143
                                                                                                                                       NAME/KEY: misc feature
OTHER INFORMATION: Incyte
                                                                                                                                                                         FEATURE:
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                    LysThrLysAlaMetAspLeuHisAlaValLeuAlaGluLeuProArgProArgArgPro
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APPLICANT: Hodge, Martin 6558908el Kinases and Us: TITLE OF INVENTION: No. 6558908el Kinases and Us: FILE REFERENCE: 35800/183781
CURRENT APPLICATION NUMBER: U$/09/345,473E
CURRENT FILING DATE: 1999-0$-30
NUMBER OF SEQ ID NOS: 62
SOFTWARE: FastSEQ for Windows Version 4.0
SEQ ID NO 9
LENGTH: 981
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Best Local Similarity
Query Match:
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                                                                                                                                                                                                                                                                                                                                  TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: misc feature
LOCATION: (1)...(981)
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